Remarks

The applicants thank the Examiner for the courtesy of the interview of March 10, 2004.

The Drawings

A portion of Fig. 1 has been indicated as showing the prior art metal coil. Figs. 2B, 2D, 2E,2G,3A,4A,4C,5A,5C, and 5E have all been indicated as depicting the prior art metal coils. Approval of the amended drawings is requested.

Claim Rejections - 35 *USC§ 102b*

Claims 1 and 11 - 13 are rejected as being anticipated by **Wallace** U.S. Patent 5,733,329 (1998). The publication date of **Wallace** is junior to the priority date of the present application and therefore is not a proper 102(b) reference.

The present application is a continuation in part of application 09/406,306 filed on Sept. 27, 1999, which in turn was related to U.S. Provisional Patent Application Ser. No. 60/072,653 filed Jan. 27, 1998. Application 09/406,306 was incorporated by reference in its entirety, page 1, lines 10- 12, as well as being substantively included in the disclosure. Application 09/406,306 in turn substantively included the entirety of U.S. Provisional Patent Application Ser. No. 60/072,653 to which it was explicitly referenced by a priority claim. Hence, with respect to the subject matter of U.S. Provisional Patent Application Ser. No.

60/072,653 the present application has a filing date of Jan. 27, 1998.

Wallace and **Vacanti**[1] which were granted and published in 1998 cannot be used as section 102(b) as references since the claimed features are disclosed in the original provisional application which predates their publication dates.

In the interview the applicants and Examiner discussed a possible basis of rejection under 35 USC 102(e). As noted Mike Wallace is employed by the licensee of the assignee of the present invention and was active in developing thrombogenic coat Pt coils which were licensed from the same assignee as the GDC coils, namely the "metal coil" prior art. Mike Wallace had no notion or idea about organizing the blood clot into scar tissue by means of inducing an inflammatory response and his patent is in no way directed to the notion. It was not known at the time how this might be done or if this could be done. **Wallace's** efforts were directed to developing coils which could fill the aneurysm, typically by mechanical means and by increased thrombogenicity.

In contrast the direction of the claimed invention is to fill the aneurysm by organizing the blood clot into tissue or inducing the bio-response to fill or heal over the aneurysm by the growth of scar tissue, apart from either the filling effect by coil or its thrombogenicity.

Wallace discloses at col. 4, lines 48 – 53, various polymers, including nonbiocompatible and nonbioabsorbable materials such a silk and cotton, none of which are claimed here. **Wallace** discloses at col. 5, lines 39 – 46, that these

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[1] The Examiner's use of **Vacanti** is confusing inasmuch as it is clearly included in the 102 section of the Office Action, but is used for "anticipation" as a single reference under "102b/103a". It is clearly not a 102b reference and the Examiner does not combine it with any other reference under 103a.

same nonbiocompatible and nonbioabsorbable materials when used in fibrous form add to the thrombogenicity of the Pt coil. The problem with the **Wallace** approach is the high incidence of recanalization, i.e. the coils embedded in the soft, unorganized thrombus are compacted by the pulsatile flow of blood and washed out of the aneurysms. **Wallace** has no and suggest no solution to this problem.

The claimed methods and structure are not anticipated element for element and do not follow in any sense from the qualitatively divergent and distinguishable **Wallace** approach.

Consider amended claim 1, which is similar to each of the pending independent claims. The is directed to a separable implant comprised at least in part of at least one biocompatible and bioabsorbable polymeric material characterized by its ability to induce controlled inflammation to induce controlled formation of scar tissue in the body cavity to substantially completely occlude the body cavity without excessive formation of scar tissue. Almost all foreign bodies implanted into tissue create some scar tissue. Even the bare prior art Pt coils induce some inflammation and scar tissue formation, but rarely, if ever, enough to completely occlude the aneurysm or to prevent recanalization. Other materials such as silk and cotton disclosed by **Wallace** are so inflammatory in their response that the typically cause tumors to form and an acceptable risk of stenosis of the adjacent vessel. What is needed is come kind of implant and method for creating controlled formation of scar tissue in the aneurysm to substantially completely occlude the aneurysm without excessive formation of

scar tissue or tumors. The invention discloses the use of a biocompatible and bioabsorbable polymeric material characterized by its ability to induce controlled inflammation. Because it is biocompatible the degree of inflammation is not excessive. Because it is bioabsorbable the inflammation which is induced is terminated when the polymeric material is absorbed and the inflammatory bio-response then decreases with the absorption and stops.

The illustrated embodiment is a mixture of polyglycolic/ poly-L-lactic acid copolymers with a 90/10 molar ratio of glycolic to L-lactic acid to control the degree of inflammatory response as set out in claim 34. The preferred polymeric material is a copolymer selected from the group consisting of poly-glycolic acid/poly-L-lactic acid copolymers, polycaprolactive, polyhydroxybutyrate/hydroxyvalerate copolymers, poly-L-lactide, and polydioxanone as set out in claim 7, but need not be limited to these materials. It is anticipated that other materials could be found having similar biocompatible and bioabsorbable characteristics coupled with a controlled inflammatory response as claimed in claims 1, 12, 34, and 51.

Claims Rejections - 35 USC 103 (a)

Claims 7 and 18 were rejected as being obvious over **Vacanti** in view of the teaching of the present application that the use of polycarbonates and polyanhyrdrides are equivalents to poly-glycolic acid/poly-L-lactic acid copolymers, polycaprolactive, polyhydroxybutyrate/hydroxyvalerate copolymers, poly-L-lactide, and polydioxanone in the present context. The Examiner

apparently makes this assertion on the basis that Applicant previously claimed polycarbonates and polyanhyrdrides with these compounds as appropriate polymers. The Applicant never makes any assertion that the two sets of compounds, polymers and copolymers, are obviously equivalent chemically or in terms of their bioeffects. Mere inclusion in a proposed claim does not in any sense lead to the conclusion that in the present context poly-glycolic acid/poly-L-lactic acid copolymers, polycaprolactive, polyhydroxybutyrate/hydroxyvalerate copolymers, poly-L-lactide, and polydioxanone are obviously equivalent to polycarbonates and polyanhyrdrides for use as a biocompatible and bioabsorbable polymer causing permanent blockage of flow of blood in the body cavity by inducing the formation of scar tissue.

There is no basis for a rejection merely from inclusion in a prior claim. There must be some teaching in the art suggesting or motivation there substitution other than the applicants' own teaching arising from inclusion in a common claim. The applicants do not believe selection of one material is obvious from the other.

Claims 30 and 47 were rejected as obvious over **Vacanti** in view of **Wallace**. It was admitted that **Vacanti** does not teach a polymer coated coil which restricts coil compaction by accelerated scar formation. The Examiner contends that restriction of coil compaction by accelerated scar formation follows from **Wallace,** because **Wallace** shows coated coils. But no such suggestion can be found in **Wallace** relating in any way to coil compaction. **Wallace** never uses the word, "compaction" in any sense. **Wallace** does not refer to any scar tissue

growth let alone any acceleration of scar tissue growth. **Wallace** describes coating coils to provide enhanced radioopacity, which is irrelevant to the invention. While **Wallace** may motivate coating coils to enhance radioopacity, it is silent with respect to any teaching of use of a polymer to restrict compaction of the coil by accelerated scar formation, to which teaching polymer coil coating for enhanced radioopacity is irrelevant.

Advancement of the claims as amended to allowance is respectfully requested.

Respectfully submitted,

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